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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,570	04/30/2001	Seonghong Jo	1789-03805	2225
23505	7590	06/15/2004	EXAMINER	
CONLEY ROSE, P.C. P. O. BOX 3267 HOUSTON, TX 77253-3267			WAX, ROBERT A	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/845,570	JO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Robert A. Wax	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-20, 23, 24 and 26-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30 is/are allowed.
- 6) ☒ Claim(s) 2-17, 19, 20, 23, 24, 26-29 and 31-34 is/are rejected.
- 7) ☒ Claim(s) 18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Introduction***

1. Upon review of the previous Office action Examiner realized that claim 6 had been inadvertently left out of the rejections and no explanation was provided for allowable subject matter. The amendments made to the claims, especially making claims 2-5 depend from 6 have overcome the previous rejections based on Rhee et al. However, the rejection over Suggs et al., which should have been applied to claim 6 in the previous Office action, is maintained. Additionally, Palladino et al. was discovered which raised further issues. The previously implied indication of allowability of claims 10,16,19, 20 and 23 is hereby withdrawn. Examiner apologizes for any inconvenience.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 9, 13, 14 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 9, the term "comprising" should read "comprises"; regarding claims 13 and 14, the term "including" renders the claim indefinite because it is unclear whether the limitations following the term are the only extracellular matrix molecules

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being claimed; regarding claim 31, the recited steps will make PPF, not OPF since poly (propylene glycol) is reacted with fumaryl chloride.

***Claim Rejections - 35 USC § 102***

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 2-7, 10, 16, 19, 20, 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Suggs et al. (5,527,864).

Suggs et al. teach a polymeric network comprising poly (propylene fumarate) copolymerized with poly (ethylene oxide) and crosslinked with an unsaturated linker monomer. They also suggest radical initiators such as acetyl peroxide, which are known to catalyze polymerization of double bounds. These teachings clearly anticipate claims 2-7 and 24. Claims 10, 16, 19, 20 and 23 are considered to be anticipated as well because once the poly (propylene fumarate-co-ethylene oxide) taught by Suggs et al. is formed the resulting polymer would be indistinguishable from polyethylene glycol fumarate also containing polypropylene oxide.

6. Claims 10, 16, 19, 20 and 23 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Palladino et al.

Palladino et al. teach a polyester prepared from fumaric acid and poly (ethylene glycol) crosslinked with N-vinyl pyrrolidone, see column 19, lines 25-27. This must be

biocompatible because it is intended for use in IP (intraperitoneal?) administration. This clearly anticipates the above claims.

***Claim Rejections - 35 USC § 103***

7. Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suggs et al.

The teachings of Suggs et al. have been outlined above. In addition they discuss varying the parameters to study the effect on the properties of the copolymer at column 3, line 58 – column 4, line 61. It is considered well within the ordinary level of skill in the art to vary proportions of ingredients to achieve desired properties, hence it would have been obvious to one of ordinary skill in the art at the time the invention was made to vary the proportions of polyethylene glycol and fumaryl chloride to achieve the desired wet to dry swelling ratio.

8. Claims 8, 9, 29 and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suggs et al. in view of Patel et al.

The teachings of Suggs et al. have been outlined above.

Patel et al. teach solid carriers for improved delivery of active ingredients in pharmaceutical compositions comprising polyoxyethylene-polyoxypropylene block copolymers (see column 25, line 60 – column 27, line 33) and various additives.

Additives can be, for example, proteins or carbohydrates including cellulose derivatives, starch and chitosan, see column 40, lines 60-63.

It would have been obvious to one of ordinary skill in the art to utilize proteins or carbohydrates as additives to the compositions of Suggs et al. in order to obtain the advantages taught by Patel et al.

9. Claims 11, 13-15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palladino et al. in view of Patel et al.

The teachings of the references are outlined above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize proteins or carbohydrates as additives to the compositions of Palladino et al. in order to obtain the advantages taught by Patel et al.

10. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Palladino et al. in view of Patel et al. and Hubbell 6,596,267.

The teachings of Palladino et al. and Patel et al. are outlined above.

Hubbell et al. teach bioactive species to be used to target adhesion of polyalkylene oxides that include RGD, YIGSR and REDV, see column 6, lines 19-23 and lines 43-60.

It would have been obvious to one of ordinary skill in the art to utilize the bioactive species taught by Hubbell et al. with the polymers of Palladino et al. as modified by Patel et al. for the advantages taught by Hubbell et al.

***Response to Amendment***

11. As stated above, the amendment obviated the rejections based on Rhee et al. Furthermore, Examiner appreciates applicant pointing out the teaching in the specification that was said to be missing; the rejection under 35 USC 112, first paragraph is therefore withdrawn. The previous rejections under 35 USC 112, second paragraph were also obviated. In view of the failure to reject claim 6 and make the above rejections under 35 USC 112, second paragraph, this Office action is nonfinal.

***Allowable Subject Matter***

12. Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The references of record do not teach use of polyethylene glycol to crosslink poly (ethylene glycol) fumarate.


***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The *Biomacromolecules* article seems germane to the instant application even though it is not prior art.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-0623. The examiner can normally be reached on Monday through Friday, between 9:00 AM and 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S. F. Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert A. Wax  
Primary Examiner  
Art Unit 1653